✳ REGIS

Ethics Application

QUICK REFERENCE GUIDE   **FOR RESEARCH APPLICANT**

Completing an Ethics Application

What is an Ethics application?

Ethical review is a key process to assess all research involving humans against ethical and scientific principles set out by the [National Health and Medical Research Council (NHMRC)](#).

As a result, all human research applicants must complete a Human Research Ethics Application (HREA). Once you have registered your project, you will need to complete and submit this form in REGIS.

Who Can Access, Edit and Submit the Application?

The person who submitted the Project Registration (if not the CPI) and the CPI have automatic 'edit' access to the HREA. The people listed at Project Registration will have VIEW access at a minimum. However, only the CPI and anyone with 'edit & submit' access can submit the application.

The CPI can give 'view', 'edit', 'edit & submit' rights to the HREA to anyone with a REGIS account.

Anyone with a REGIS account can have the application shared with them, they do not need to be a member of the research team.

How does it work in REGIS?

The overall process of completing the HREA in REGIS is show in the next column.

Navigate to the application

Complete all sections of the HREA

Review, certify and generate HREA
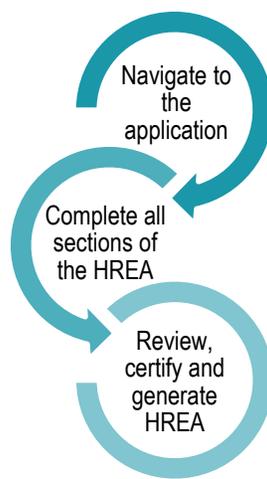
Completing The Ethics Application

Step 1: Navigate to the application
If you are completing directly after project registration, select the ETH identifier.

⇕ Identifier
2020/ETH00024

If completing at a later stage, from the home page select the 'Projects' icon at the top of the screen to view a list of Projects you have access to.

🖥 Projects

Select the relevant project from the list. Once in the project details, the HREA will appear with an ETH identifier and will be in the status of 'In Progress'.

Step 2: Complete all sections of the HREA
Once on the HREA introduction page, you can see all the sections that you need to complete in the left-hand side panel. As you work your way through the application, questions and fields that must be completed are marked with an *

Details provided in the Project Registration will appear in the HREA.

The following details will only describe where there are system requirements to be aware of to complete the form.

Q1.9 Project Team Details:
1.9.1 – 1.9.3 will show all people added at Project Registration, including the Principal Investigator and administration contacts. If an administration contact was given submit access during Project Registration, and the CPI has approved it, they will then have **1.9.5** & **1.9.11** answered as 'Yes'. This means that they can submit the application.

The CPI or users with 'Submit' access can submit the ETH Application. The information provided at Project Registration pulls through to the ETH.

CPI – This person will be the first person in the table. If this person is also a site PI, they will appear multiple times – **do not remove.**

The person listed as **CPI** must have the following response in HREA (this has been prefilled).

    1.9.10   **MUST** be Coordinating Principal Investigator.

PI/s – Site PI/s added at Project Registration will appear under the CPI

Administration Contact – Admin contacts added at Project Registration will appear under the PI.

If the administration contacts have not been specified during Project Registration, they can be added here but cannot be given submit access in the

application. This will have to be done using the 'Invite to Share' button.

AI/s or Project team members - Any other research team members that are required to be assessed by the HREC should be added here.

Updating Documents Uploaded at Project Registration

If any of the documents uploaded during project registration have been updated or edited, the final version will need to be uploaded before the HREA is submitted.

Protocol: To update the Protocol with a new version select 'Clear content selection' and follow the wizard.

Clear content selection
(KCTP_Protocol_REGIS.docx) [Open]

Other Documents: To update any other study wide documents 'Clear content selection' and follow the wizard to then update the description of the attachment including the version and date.

Add New Documents to HREA

To add any study wide documents, click the plus icon '+' at the bottom of the screen, select 'Upload New' and follow the wizard.

Document Type: Select from dropdown.

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Note: How the document is described is how it will appear on the approval notification.

Q4.3 –Q4.7 HREC

Confirm the institution and HREC/ethics review body where you will be submitting your application. It is important to select the correct Ethics Review Pathway as an incorrect selection will delay review of your application.

If you are unsure of what review pathway your Ethics application should be

reviewed under, contact the reviewing Research Office to discuss.

Step 3: Review, Certify and Generate HREA

The following sections **must be completed by the CPI or anyone with 'Submit' access**, as delegated by the CPI (who has overall responsibility of the study)s. Only one person is required to certify the application on behalf of everyone else named in this section.

Q4.7 Declaration

The first person appearing here will be the CPI. Anyone with submit access will appear underneath the CPI. If the CPI's name is not appearing return to 'Project Teams' and review responses.

Generate HREA Document

Generate = Submit to Research Office.

Only the CPI or anyone with 'Submit' access will have the option to submit the HREA. Click the 'Generate HREA document' button once you are ready to submit the application. Alternatively, you can save your progress and return to your form later.

Once the ethics application (HREA) has been submitted:

❖ A pop up on your screen allows you to download a .zip file of the application forms and attachments. This is useful for multi-centre studies that require document submission to other jurisdiction application portals.
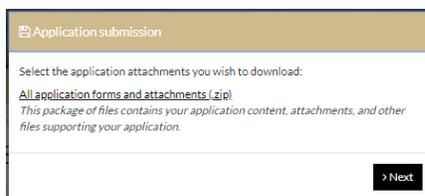
❖ The status of the application will be 'Submitted' and the Research Office will proceed to assess the HREA for eligibility to be reviewed by the HREC.
❖ Any NSW Site application/s will now be created for each site listed at

project registration. See **Quick Reference Guide/video:** *Site Application – Completing, Requesting Head of Department Support and Submitting.*

What Is My Review Pathway?

As described in the national statement on ethical conduct in human research:

More/Greater than low risk
"Research with more than a low level of risk (as defined in paragraph 2.1.6,) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21. Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23)."

Low and Negligible risk
"2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk."

"2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk."

For further assistance if needed, contact your local research office at these links – NSW or ACT.